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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,489	03/01/2004	Keith Allan Freehauf	MER 03-017	9517

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,489	FREEHAUF, KEITH ALLAN	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 9-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 9-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Amendment filed February 4, 2009 is acknowledged. Claim 8 is canceled. Claims 1, 2, 4-7 and 9-24 remain under consideration.

An Information Disclosure Statement filed January 7, 2009 is further acknowledged and has been reviewed.

An amendment to page 10, second paragraph, of the specification is noted.

The instant specification claims the benefit of prior-filed U.S. Provisional Application No. 60/530939, filed December 19, 2003. However, support for the amount of antioxidant of the premix of claim 24, i.e., "about 0.5% (w/w)," was not found in the provisional application on page 6, or pages 9-10, as Applicant stated. On the contrary, the entire premix formulation of claim 24 appears to be that described on page 9.

In a most preferred embodiment the instant invention provides for a stabilized premix feed or feed-like formulation for the treatment or prophylaxis of parasite infestation in swine and horses with an extended shelf life comprising:
(a) **0.618%** (w/w) of ivermectin,

(b) a pharmaceutically or veterinary acceptable excipient consisting of:
(i) **8%** (w/w) of polyoxyl 40 hydrogenated castor oil;
(ii) **21%** (w/w) of distilled monoglycerides;
(iii) **0.9%** (w/w) of oil soluble antioxidants wherein said antioxidants are selected from the group consisting of butylated hydroxyanisole, propyl gallate, anhydrous citric acid, and propylene glycol;
(iv) qs 100% (w/w) of fine ground com cobs; and

(c) **0.48%** (w/w) increase w/w of anhydrous citric acid.

As is readily apparent, each of the ranges in claim 24 corresponds to this preferred embodiment except part (b), iii), which is recited to be "0.5%" but is 0.9% *supra*.

With respect to the concentration range of the premix of claim 24, this limitation is not found in the provisional application in the preferred embodiment in which all concentration ranges correspond to claim 24 except the one described *supra*. As such, the earliest effective U.S. filing date of the instant application is determined to be March 1, 2004.

Claims 13 and 24 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Support for the range as clearly noted above is absent. The rejection of claim 24 is maintained. The rejection of claim 13 is withdrawn.

See *In re Rasmussen*, 211 USPQ 323 (CCPA 1981).

Claims 1, 2 and 4-23 remained rejected under 35 U.S.C. 103(a) as being unpatentable over Jancys, A.H., U.S. Patent 6,489,303, in view of Katoh et al., U.S. Patent 4,939,166, Chabala et al., U.S. Patent 4,199,569, Sutherland et al., U.S. Patent 4,910,219, Freehauf et al., U.S. Patent 7,001,889, and Carson et al., U.S. Patent 6,548,478, in the last Office Action.

Jancys teaches anthelmintic compositions comprising avermectins, such as ivermectin, abamectin, doramectin, selemectin and moxidectin, in column 2, lines 37-39, or derivatives thereof, in which stabilizers – which are antioxidants - are added in an amount of about 0.15% to about 5%. See column, lines 62-64. Jancys teaches suitable

carriers for veterinary compositions are known in the art. See column 4, lines 27-34. In a preferred embodiment Jancys teaches citric acid to act synergistically with some antioxidants, such as butylated hydroxyanisole, and it may be necessary to include extra citric acid to achieve stability of the composition. The inclusion of additional citric acid is disclosed in column 4, lines 1-10 and 24-25. See the Discussion in column 9. lines 37-51. The simple presence of citric acid does not result in adequate stability. Thus, Jancys recognized and addressed the instability issues of avermectin compositions. His teaching encompasses the desirability of adding additional citric acid to achieve stability.

With respect to the requirements of the present claims for pharmaceutically acceptable surfactants, waxes, antioxidants, carrier vehicles and, optionally, insect growth-regulating compounds in animal feed compositions comprising avermectins:

Chabala teaches feed premixes comprising avermectins utilize carriers such as corn meal, citrus meal, fermentation residues, ground oyster shells, wheat shorts, molasses solubles, corn cob meal, bean mill feed, soy grits, dried grains and crushed limestone. See column 8, lines 11-21. Further, Sutherland teaches compositions for veterinary medicine comprising macrolides of formula II may be formulated to include the waxes glyceryl monostearate or coconut oil. See column 5, line 16. Katoh broadly teaches the inclusion of surfactants in a premix for an animal feed comprising macrolide compounds that are structurally analogous to avermectins. See column 10, lines 40-43, and column 14, lines 5-8. Carson teaches the inclusion of anhydrous citric acid in foodstuffs such as feed grain

comprising macrolide antibiotics. See the Examples. As required by instant claim 13, the amount should be sufficient to provide a pH of from about 3.0 to about 7.0 in order to minimize the breakdown of the components of the mixture. See column 1, lines 51-61, and column 2. Freehauf teaches the inclusion of avermectins in oral compositions intended for swine or equine administration, wherein pH stabilizers such as maleic acid or citric acid, antioxidants, such as sodium metabisulfite or ascorbic acid, and surfactants, such as hydrogenated castor oil, are further included.

Each of Carson's "preferred formulation" and Examples 1-3, columns 3 and 4, may be properly characterized as a "premix" in that each is a mixture that is preferably maintained as substantially anhydrous prior to forming a suspension, in order to minimize the breakdown of the components of the mixture. According to Carson, the shelf life can be maximized. See lines 1-2, column 3. Thus Carson teaches a premix comprising stabilizers that are incorporated for the purpose of extending the shelf life of the veterinarian antibiotic formulation.

Claims 1, 2 and 4-23 employ open (comprising) language. The premix of instant claim 1 and the method of extending the shelf life of a premix are open to the inclusion of any number, and any type, of additional active or inactive agents. Further, a paste qualifies as a premix in that it is an oral composition intended for administration to warm-blooded animals or birds. The anthelmintics are dissolved in a solvent, but then they are dispersed in a carrier matrix which is a paste. The paste is formed by the addition of thickeners and opacifiers. See column 8 lines 13-27. Preferred ranges for pH are about 4 to about 6.5. The buffers contemplated to stabilize the formulations are

recited in column 8, line 60, to column 9, line 1. The resultant oral veterinary paste is a soft solid. Freehauf teaches such pastes achieve a better bioavailability of anthelmintic agents than when the active agent is in suspension.

With respect to the Jancys reference, Applicant argues Jancys does not recite the amount of added citric acid or sodium citrate required to result in a pH range between 4-6.

A pH range is not herein claimed. Jancys states the purpose of the extra citric acid is to stabilize the formulation. It is noted the amount of "both the extra antioxidant and citric acid to allow the stability levels needed" is "between about 0.1% and 1.5%." Therefore, Jancys teaches a combined amount that encompasses both amounts recited in the present claims.

With respect to the Carson reference, Applicant argues Carson relates to virginiamycin, a macrocylcic peptide-based antibiotic, that has no structural similarity to the avermectin family.

The Examiner agrees that although the antibiotics are both macrolides, they are structurally different. The Carson reference is applied as a general teaching merely to establish that the inclusion of anhydrous citric acid in foodstuffs, such as animal feed, and in macrolide antibiotic formulations, was known in the prior art.

With respect to the Freehauf reference, Applicant argues the patent does not meet the criteria to qualify as prior art under 35 U.S.C. § 102(e) and asserts the rejection of record under 35 U.S.C. 103 is improper. Applicant urges the reference is not by "another," as required by 35 U.S.C. § 102(e).

The determination of the issue is based on whether or not there was a common assignment at the time of the invention.

Applicant further argues in making an obviousness determination, commercial success and unexpected results, in particular, are considered.

An allegation of commercial success is insufficient. A Declaration is required. Further, a review of the specification fails to provide a showing of unexpected results that is commensurate in scope with Applicant's general statement of "unexpected results." Example 1 on page 15 of the specification describes a single formulation.

In view of the combined teachings of the prior art, one skilled in the veterinary art would have been motivated to prepare a premix for an animal feed comprising at least one avermectin in combination with a pharmaceutically acceptable surfactant, wax, antioxidant, stabilizer, carrier vehicle and an additional amount of citric acid, with a reasonable expectation of having an extended shelf-life of the formulation. The rejection of claims 1, 2, 4-7 and 9-24 under 35 U.S.C. 103 is maintained because the problem of stability of premix compositions comprising avermectins is successfully addressed by Jancys. The inclusion of anhydrous citric acid in animal feed will minimize the breakdown of the components of the mixture and extend the shelf life of the product.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

No claim is allowed.

Applicant's request for an interview is noted.

Applicant may contact the Examiner to establish an interview time and date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 5, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614